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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,236	08/29/2001	Richard A. Hillstead	HILL 100	9154

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EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/04/2003

85

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,236

Applicant(s)

HILLSTEAD ET AL.

Examiner

D Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on IDS 6/24/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-39, 41-43, 53-62, 64-66, 68-71, 73 and 79 is/are rejected.
- 7) ☒ Claim(s) 40, 44-52, 63, 67, 72 and 74-78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "electrodes carried by said jaws" of claim 56, "scissor blade" of claim 57, and "remote hydraulic fluid pressure source," "remote robotic controller," and all other limitations of claim 79 must be shown or the features canceled from the claims. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

Claim 50 is objected to because of the following informalities: the claim depends from itself. Examiner considers the claim depending from claim 44. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-20, 31-37, 39, 41, 42-43, 56-57, 66 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, 31, 37, 42 and 56 respectively recite the limitations, "the first jaw," "the hydraulic pressure source," "the first and second jaws," "the first jaw...the second jaw," and "said jaws." There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10, 13, 14, 23-25, 28, 31, 32, 34, 38, 39, 53, 64, 65, 68, 70, 71 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Schichman (US 4,488,523). Schichman discloses a hydraulically actuated medical stapler (Fig. 1) comprising shaft 10, end effector 12, 18 and 20, handle portion 14, flexible fluid flow paths 80 and 140, and two articulation joints. The first articulation resides at the junction of elements 16 and 154 (Fig. 6) and the second resides at the junction of elements 16 and 12 (Fig. 4). Figs. 6 and 4 illustrate how the fluid flow paths are in

proximity to the articulation joints. The distal articulation joint is moved laterally to advance/retract the end effector.

The device comprises an end effector 12, 18 and 20 comprising first 132 and second 84 hydraulic actuators (Fig. 4), first 140 and second 80 hydraulic fluid flow paths, and first 170 and second 232 hydraulic pressure sources (Fig. 6). The device further comprises a hydraulic cylinder block 40 (Fig. 4) that communicates with a fluid path, a piston 132, and a trigger/lever 32. As pressure is applied to the piston 132, the pressure forces the piston to actuate. At the same time, the piston exerts a force on the hydraulic system thus increasing the pressure. The end effector is biased to a position of lower hydraulic pressure.

The two hydraulic actuators effect two different actions. The first actuator 132 advances/retracts the end effector while the second actuator 84 ejects a staple.

Claim 79 is rejected under 35 U.S.C. 102(b) as being anticipated by Cohn et al. (US 5,791,231). Cohn discloses a hydraulically actuated robotic medical instrument comprising a hydraulically actuated end effector 80 (Fig. 4B), an elongated shaft 54, a remote hydraulic fluid source 40 (Fig. 3), hydraulic fluid flow paths 92 and 94, and a remote robotic controller 16 (Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3731

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shichman. He discloses the use of a "release tab" 33 that is used to maintain the lever, but fails to disclose that the "release tab" 33 maintains the lever in an increased pressure state. Nevertheless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide another release tab of a smaller size such that it maintains the lever in an increased pressure state so that the end effector can hold tissue without requiring effort by a surgeon.

Claims 14-19, 21, 22, 31, 36, 37, 41-43, 53, 54, 55, 58-62, 64, 66, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shulze et al. (US 5,632,432) in view of Shichman. Shulze discloses a mechanically actuating stapler having jaws 142 and 132 for stapling. The jaws comprise an anvil 140 and a second jaw 132 having a cartridge 150 with staples. He does not disclose a hydraulically actuated stapler. Nevertheless, Schichman teaches the use of a hydraulically actuated stapler. Hydraulically actuated staplers allow surgeons to exert less input force to achieve a greater output stapling force. In other words, a mechanical advantage is achieved to reduce stress to a surgeon's hand (Col. 3, lines 8-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to substitute Schulze's mechanically actuated stapling system for a hydraulic one as taught by Shichman. The substitution creates a mechanical advantage that reduces stress to a surgeon's hand.

In general, the Schulze/ Shichman device comprises Schulze's body with the hydraulic actuation system taught by Shichman. The device comprises an actuator 176 as taught by Shichman that moves Schulze's jaws, which are biased apart as illustrated in Fig. 1. The first actuator 132 is a piston having a linkage 248, 252, 254 (Shichman, Fig. 6) associated with the piston to actuate the jaws.

Claims 1, 8, 9, 14, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blanco et al. (US 5,348,259) in view of Shichman. Blanco discloses a mechanical mechanism for actuating the surgical stapler. He fails to disclose hydraulic actuators. Nevertheless, Shichman teaches the use of hydraulic actuators to effect stapling in a surgical stapler to increase mechanical advantage as heretofore described. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Blanco stapler to use hydraulic actuators to increase the mechanical advantage as described previously. Blanco discloses ball and socket articulation joints 12 that permit 360 degrees of articulation.

Claims 1, 11, 12, 14, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (US 5,381,943) in view of Shichman. Allen discloses a mechanically actuated surgical stapler, and fails to disclose a hydraulically actuated

stapler. Nevertheless, Shichman teaches the use of a hydraulically actuated stapler to increase mechanical advantage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Allen stapler to hydraulically actuate the stapler to increase mechanical advantage as described previously. Allen discloses a hinge type articulation joint 390 (Fig. 33) that is manipulated by cable 418 (Col. 15, line 67--et seq.).

Claims 53 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates et al. (US 5,403,312) in view of Shichman. Yates (Fig. 1) discloses a stapler having jaws and an RF cutting instrument connected to a generator 60 via wires 19 and 20. Yates fails to disclose that the RF/staple jaws are actuated hydraulically. Nevertheless, Shichman teaches the use of a hydraulically actuated surgical stapler to increase mechanical advantage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to alter the Yates device as taught by Shichman to hydraulically actuate the stapler to increase mechanical advantage. Additionally, Yates discloses a way to cut tissue, including scissor blades having electrodes (Col. 2, lines 17-23), but does not teach that such a way may be combined with his device. Nevertheless, it is a well known way to cut tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include scissor blades with the stapler to cut tissue as disclosed by Yates.

Allowable Subject Matter

Claims 40, 44-52, 63, 67, 72, and 74-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20 and 33 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD
June 1, 2003



Michael J. Milano
Supervisory Primary Examiner
AU 3731